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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,495	07/23/2003	Chih-Feng Lin	089048/0292	7833

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,495	LIN, CHIH-FENG	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The application should be reviewed for errors. Error occurs, for example, in the spelling of "manitol" in claim 4.

The status of the parent case(s) should be updated.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of the strain of interest as a probiotic, does not reasonably provide enablement for "treatment and prophylaxis of gastroenteric disorders in a subject in need of such treatment or prophylaxis" for the strain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

From the record of the present written disclosure it is apparent that the strain can survive and grow well when ingested and that it resists certain antibiotics. However, this cannot be equated with the prevention and treatment of all possible gastroenteric disorders, including cancers, Crohn's disease, food allergies, etc. etc.. Clearly the treatment of cancer, for example, could not be deemed predictable at the time the claimed invention was made and cannot be deemed so at present. There is a large number and variety of types of cancers that are recognized by those of ordinary skill in this art to affect the gastrointestinal tract, such as of the mouth, esophagus, stomach, colon, etc., and not even for one type of cancer has a predictably successful treatment been achieved, even when a variety of approaches are combined, including radiation, surgery and chemotherapy of various types and natures. Methods of predictably preventing cancer are not known.

The record shows results *in vitro* but does not show that the teachings provided in the as-filed specification are sufficient to enable one skilled in the art to practice the invention as claimed. The guidance provided in the specification is not adequate to lead one skilled in the art toward success in treating or preventing all of the diseases that can be deemed to constitute "gastroenteric disorders" in any subject in a predictable manner.

See Genentech, Inc. v Novo Nordisk A/S., 42 USPQ2d, 1001, 1005 (Fed. Cir. 1997) ("Tossing out the mere germ of an idea does not constitute an enabling disclosure"). Also, In re Scarbrough, 182 USPQ 298, 302 (CCPA 1974) ("It is not enough that a person skilled in the art, by carrying out investigations along the line indicated in the instant application, and by a great amount of work eventually might find out how to make and use the instant invention. The statute requires the application itself to inform, not to direct others to find out for themselves. In re Gardner et al., 166 USPQ 138 (1970)").

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

Claim Rejections - 35 USC § 112

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a novel strain of *l. rhamnosus* having specific properties. The written description of that strain and the method of isolating is insufficiently reproducible. Therefore, a deposit for patent purposes is required. The specification discloses at page 6 that the strain was deposited at the ATCC with accession number PTA-2406 under Budapest Treaty conditions on August 22, 2000.

For compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and **that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.** MPEP 2403.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 5-8 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bengmark *et al.* or Gill *et al.*.

The claims are drawn to an *L. rhamnosus* strain which is suitable for the treatment or prophylaxis of gastroenteric disorders in probiotic amounts and process of using the strain for the treatment or prophylaxis of gastroenteric disorders.

The cited reference discloses an *L. rhamnosus* strain which appears to be identical to the presently claimed strain (See, e.g., Bengmark *et al.*, col. 9 and col. 11-12; Gill *et al.* Examples 2-5), since it is suitable for the treatment or prophylaxis of gastroenteric disorders in probiotic amounts. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism, since it is of the same class as that of the microorganism claimed and is taught to be effective against the same conditions. Consequently, the claimed strain and process of using the strain for the treatment or prophylaxis of gastroenteric disorders appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain and process would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bruce *et al.* or Mayra-Makinen *et al.* or Reid *et al.*.

The claims are drawn to an *L. rhamnosus* strain which is suitable for the treatment or prophylaxis of gastroenteric disorders in probiotic amounts and process of using the strain for the treatment or prophylaxis of gastroenteric disorders

The cited reference discloses an *L. rhamnosus* strain which appears to be identical to the presently claimed strain (See, e.g.,Bruce *et al.,* Table 2 or Mayra-Makinen *et al.,* Examples or Reid *et al.*, col. 6 and Example 10), since it is suitable at least for the prophylaxis of gastroenteric disorders in probiotic amounts. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism, since it is of the same class as that of the microorganism claimed and is taught to be effective against the same type of conditions. Consequently, the claimed strain and process of using the strain for the treatment or prophylaxis of gastroenteric disorders appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain and process of using would have been obvious to those skilled in the art within the meaning of USC 103.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bengmark *et al.* taken with Gill *et al.*, Bruce *et al.*, Mayra-Makinen *et al.*, Reid *et al.* and further taken with Fujimori (U.S. Patent No. 5,294,458), Gyorgy (U.S. Patent No. 2,694,640) and Khatchatrian *et al.* (U.S. Patent No. 6,368,641).

Each of Bengmark *et al.*, Gill *et al.*, Bruce *et al.*, Mayra-Makinen *et al.* and Reid *et al.* teach a strain of *L. rhamnosus* strain which is suitable for the treatment or prophylaxis of gastroenteric disorders in probiotic amounts and process of using the strain for the treatment or prophylaxis of gastroenteric disorders, as discussed *supra.*

The references differ from the invention as claimed in that the use of specific excipients and the use of mixed cultures is not recited. However, Fujimori discloses the use of lactosucrose in pet food to promote the growth of lactic acid bacteria in the animal gastrointestinal tract (See, e.g., col. 4, lines 50 et seq.), while Gyorgy discuss the use of chitin and/or chitosan to promote the growth of *Lactobacillus* in the gastrointestinal tract of human infants (See, e.g., col. 5).

Khatchatrian *et al.* discuss the use of chitin and/or chitosan as a carrier for *Lactobacillus* because of their recognized promotion of growth, as well as the use of mixed cultures. See, e.g., Example 3.

One of ordinary skill in the art would have had compelling motivation to provide materials such as lactosucrose and/or chitosan in probiotic compositions of *L. rhamnosus* because of their recognized favorable properties and in order to promote the growth of these microorganisms in the gastrointestinal tract upon administration as probiotics.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the compositions of *L. rhamnosus* of Bengmark *et al.*, Gill *et al.*, Bruce *et al.*, Mayra-Makinen *et al.*, and/or Reid *et al.* by providing them in mixed cultures or in compositions with excipients such as lactosucrose or chitosan as suggested by the teachings of Fujimori, Gyorgy and Khatchatrian *et al.* for the expected benefit of promoting the growth of the *L. rhamnosus* strain upon provision to the gastrointestinal tract as probiotics alone or together with other beneficial strains in order to increase their effectiveness.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651